

REMARKS

Reconsideration is requested.

Claims 1-15 and 23 have been canceled, without prejudice. The Examiner is requested to appreciate that claim 23 has canceled, without prejudice, in an Amendment filed October 29, 2007.

Claim 16 has been revised, without prejudice, to include a conclusion consistent with the preamble and in response to the Examiner's comment on page 4 of the Office Action dated November 29, 2007. Claim 35 has been added and finds support, for example, in aspect (c) of claim 1 as originally-filed. Claim 36 has been added and finds support, for example, on page 8, line 14 of the specification. No new matter has been added. Claims 37-54 have been added and are similar to claims 17-22 and 24-35 but for the dependency from new claim 36. No new matter has been added.

Claims 16-22 and 24-34 are pending. Claims 16-22 and 24-54 will be pending upon entry of the present Amendment. Entry of the present Amendment is requested.

The Section 103 rejection of claims 16-34¹ over Barclay (U.S. Patent No. 5,882,703), is traversed. The Section 103 rejection of claims 16-34 over Higashiyama (U.S. Patent No. 6,746,857), is traversed. The Section 103 rejection of claims 16-34 over Kawashima (U.S. Patent No. 5,322,780), is traversed. The Section 103 rejection of claims 16-34 over Akimoto (U.S. Patent No. 5,128,250), is traversed.

Reconsideration and withdrawal of the rejections are requested in view of the following distinguishing comments as well as the comments and remarks of record.

¹ As noted above, claim 23 has been previously cancelled, without prejudice.

The presently claimed invention provides a process for the production of arachidonic acid (ARA), the process comprising culturing a micro-organism which is *Mortierella* in a culture medium inside a fermentation vessel, whereby at a stage which precedes the end of fermentation, a carbon source is added at a rate below the rate of consumption of the carbon source by the micro-organisms. The claimed process requires production of arachidonic acid.

The Examiner has characterized the unamended claims as defining a method which

"requires a first stage for the culturing a microorganism from the genus *Mortierella* and a second stage which precedes the end of fermentation (EoF) adding ... a carbon source is added at a rate below the rate of consumption of the carbon source by the microorganisms."

As noted above, claim 16 has been further revised to specifically require production of arachidonic acid, as will be understood by one of ordinary skill in the art to have been required by the preamble of the unamended claim.

The claimed invention would not have been obvious in view of either Kawashima or Akimoto as, for example, neither cited patent teaches or suggests a method of producing arachidonic acid.

More specifically, Kawashima fails to teach or suggest, for example, (i) a process for the production of arachidonic acid (ARA) and (ii) adding the carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms

Regarding (i), it is noted that Kawashima is understood to relate to a process for the production of omega 9 polyunsaturated fatty acids (PUFA), see e.g. title. The

Examiner will appreciate that arachidonic acid is an omega-6 PUFA, and not an omega 9 PUFA.

The process of Kawashima involves mutation of a micro-organism having an ability to produce ARA to generate a mutant capable of producing omega 9 polyunsaturated fatty acids (col. 2, lines 40-61). The mutants of Kawashima do not produce ARA, as required by the presently claimed process. This is also seen in the examples, tables 1 and 2 of the cited patent. The amount of arachidonic acid produced (designated as "Ara" in the tables, 3rd column from the right) by the process of Kawashima is 0 (zero). Hence, Kawashima does not disclose or suggest a process for the production of ARA, as required by the presently claimed invention.

Further, the feed profile for the carbon source of the presently claimed invention is not disclosed or suggested in Kawashima. Moreover, Kawashima fails to teach or suggest the addition of a carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms, resulting in an increased ARA content in the oil, as presently claimed.

Kawashima fails to teach or suggest production of ARA, as required by the presently claimed invention, and the process of Kawashima teaches away from production of ARA, in that omega 9 polyunsaturated fatty acids (PUFA) are produced by the process of Kawashima.

The claims are patentable over Kawashima and withdrawal of the Section 103 rejection based on Kawashima is requested.

With regard to Akimoto, the applicants note that the cited patent also fails to teach or suggest at least (i) a process for the production of arachidonic acid (ARA) and (ii) adding the carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms.

Regarding (i), it is noted that Akimoto relates to a process for production of highly unsaturated fatty acid having odd number of carbon atoms. Arachidonic acid is a PUFA having 20 carbon atoms. Accordingly, Akimoto teaches the production of a PUFA which is different from ARA, and the presently claimed invention.

Regarding (ii), it is noted that Akimoto does not disclose or suggest any feed profiles for the carbon source. The examples of Akimoto are understood to disclose fermentation in an Erlenmeyer flask (shake flask) in which all carbon source is added at once prior to the onset of the experiment. Accordingly, Akimoto does not disclose or suggest adding a carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms, as required by the presently claimed invention.

Moreover, Akimoto fails to disclose or suggest addition of a carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms, resulting in an increased ARA content in the oil, as provided by the presently claimed invention.

Finally, the PUFA which is the subject of Akimoto is not ARA, but a PUFA having an odd number of carbon atoms. Accordingly, Akimoto does not provide any teaching or suggestion of how to increase the ARA content in the oil.

The claims are patentable over Akimoto and withdrawal of the Section 103 rejection based on Kawashima is requested.

The claims are submitted to be patentable over Barclay (U.S. Patent No. 5,882,703), and consideration of the following in this regard is requested.

Barclay does not disclose or suggest adding the carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms, as required by the present claims. The Examiner is urged to appreciate that the claims define a process. Barclay fails to teach or suggest the claimed process requirements.

Examples 1-5 of Barclay is understood to describe culturing *Mortierella schmuckeri* in shake flasks wherein the carbon source is added at once prior to the onset of the experiment.

Example 6 of the cited patent is understood to describe culturing *Mortierella schmuckeri* in a fermentor. However, no feed profile for the carbon source is disclosed other than that all carbon source is added at once, i.e. a medium having a specific composition is prepared (see col. 14, lines 57-61). There is no teaching or suggestion in Barclay that a carbon source is added during the course of the fermentation. There is no teaching or suggestion in Barclay of adding of carbon source at a certain rate, let alone adding of a carbon source at a rate below the rate of consumption by the micro-organisms, as claimed.

In conclusion, Barclay does not teach or suggest adding a carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms, as claimed.

Even less does Barclay provide any teaching or suggestion that adding the carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms results in a increased ARA content in the oil, as claimed.

Withdrawal of the Section 103 rejections based on Barclay is requested.

The claims are submitted to be patentable over Higashiyama (U.S. Patent No. 6,746,857), and consideration of the following in this regard is requested.

Higashiyama fails to teach or suggest adding the carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms, as required by the claims.

Higashiyama is understood to describe adding a carbon source in the following manner:

In Examples 1, 2, 3 and 5 of Higashiyama, "The glucose concentration was maintained at between 1% and 2% using fed-batch method till day 4 and at between 0.5 and 1% thereafter";

In Example 4 of Higashiyama, the glucose concentration was maintained at 1.5% until day 5 and no glucose was added thereafter. Glucose was depleted at the end of culturing for 7 days; and

In Example 7 of Higashiyama, 18% glucose was added in several portions from day 1 through day 5 of culturing.

None of the examples or other description of Higashiyama teach or suggest addition of a carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms, as claimed. This is further shown below

In Examples 1, 2, 3 and 5 of Higashiyama, the glucose concentration is maintained at a constant level, both in the first period as well as in the last period. One of ordinary skill in the art will appreciate that in each of these periods the rate of addition of the carbon source is equal to the rate of consumption of carbon source by the micro-organism.

However, according to the presently claimed invention, the rate of addition of the carbon source is below the rate of consumption of the carbon source by the micro-organisms, which has the effect that the concentration of carbon source decreases in time during the addition of the carbon source.

Accordingly, neither of the examples 1, 2, 3, or 5 of Higashiyama disclose that the carbon source is added at a rate below the rate of consumption of the carbon source by the micro-organisms.

In example 4 of Higashiyama, the glucose concentration is maintained at a constant level until day 5. As discussed above, one of ordinary skill in the art will appreciate that in this period the rate of addition of the carbon source is equal to the rate of consumption of carbon source by the micro-organism.

However, according to the presently claimed invention, the rate of addition of the carbon source is below the rate of consumption of the carbon source by the micro-organisms, which has the effect that the concentration of carbon source decreases in time during the addition of the carbon source. After day 5, no glucose is added.

Hence in this period, the requirement of the claim that carbon source is added at the claimed rate is not met. Accordingly, in example 4, of Higashiyama, the carbon

source is not added at a rate below the rate of consumption of the carbon source by the micro-organisms.

In example 7 of Higashiyama, 18% glucose was added in several portions from day 1 through day 5 of culturing. This does not provide any information on the rate at which carbon source is added as the amounts of glucose are not given. There is no disclosure or suggestion in Higashiyama that the carbon source is added at a rate below the rate of consumption of the carbon source by the micro-organisms.

As discussed above, Higashiyama fails to teach or suggest that a carbon source is added at a rate below the rate of consumption of the carbon source by the micro-organisms. Even less is there any teaching or suggestion in Higashiyama that the addition of a carbon source according to the invention results in an increased ARA content in the oil. Higashiyama fails to teach or suggest any ARA-content of the oil.

Withdrawal of the Section 103 rejections based on Higashiyama is requested.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned in the event anything further is required.

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Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /B. J. Sadoff/
B. J. Sadoff
Reg. No. 36,663

BJS:
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100